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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,905	10/07/2003	Stephen D. Pacetti	50623.243	6361

7590 06/11/2007  
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EXAMINER
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CAMERON, ERMA C

ART UNIT	PAPER NUMBER
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1762

MAIL DATE	DELIVERY MODE
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06/11/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/680,905	PACETTI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	/Erma Cameron/	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 25-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 25-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 4/6/2007.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 5, 7-11, 16-20, 23, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Schueller et al. (US 2002/0050220).

Schueller et al. ('220) teach a method of coating (page 2, [0009]) a tubular implantable medical device such as a stent (page 11, [0084]), comprising depositing a transferable material, i.e. coating composition on the stamping surface, i.e. applicator, and transferring at least some of the layer of the coating composition onto a tubular implantable device. Examiner notices implantable stents for insertion into the blood vessel would inherently have tubular shape.

Schueller et al. ('220) further teach (page 7, [0059]) the stamp, i.e. applicator is mounted on a

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rotor and placed in contact with stent. The stent is advanced against the applicator and the applicator rotated to match the advance. The applicator may also be rotated and the stent translated to match its rotation, or the applicator may be rotated and translated on a fixed stent.

As for claims 7,8:

Schueller et al. ('220) teach (page 11, [0084]) the medical device is stent. Further, the coating composition (page 2, [0009]) comprises a polymer and a solvent, and optionally a therapeutic substance (page 11, [0083]).

As for claim 16:

Schueller et al. ('220) teach (page 4, [0038]) the surface of the stamp, i.e. the applicator is flat.

As for claim 17;

Schueller et al. ('220) teach (page 4, [0038]) the surface of the stamp, i.e. the applicator is cylindrical in shape.

As for claims 5, 11 and 20:

Schueller et al. ('220) teach (page 6, [0049]) the layer of the coating composition is transferred to the exterior of a columnar substrate, i.e. stent and that the interior surface of the stent is not exposed to the coating composition. Alternatively, (page 6, [0050]) the composition is applied to the interior surface of the stent only.

As for claim 4, 10 and 19:

Schueller et al. ('220) teach (page 6, [0046] and see Fig .4) the cylindrical applicator is mounted in an apparatus, and the tubular stent is supported by end tubing, i.e. mandrel.

As for 23:

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Schueller et al. ('220) teach (page 2, [0008]) and see Fig. 4) the applicator has a radius of curvature about equal to a radius of curvature of the tubular device.

4. Claims 1, 4, 5, 9-11 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Research Disclosure Database Number 434009, published in June 2000 by Mason publications, Hampshire, GB – ISSN 0374-4353; Title: Drug Loading Device for Drug Delivery or Coated Stent.

RD article number 434009 teaches a method (page 975, paragraph 2, 3 and fig. 1) of coating a tubular stent by mounting the stent on a mandrel, and rolling the stent on a carrier such as a sponge soak with the coating composition, i.e. applicator with a layer of coating composition, and transferring a least some of the coating composition such as a solution or a tacky polymer and therapeutic agent paste onto the outer surface of the stent, thus Research Disclosure article no. 434009 meets the limitation of claims 1, 4,5 and 9,10,11.

As for claims 17, 41:

RD article number 434009 further teaches (fig.2) the coating composition can be loaded onto the stent by submerging a portion of the stent in a cylindrical cup filled with coating solution, and rotating the mandrel along a longitudinal central axis of the stent while the stent is partially submerged in the coating solution.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2, 3, 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Research Disclosure Database Number 434009 (reference cited above)

Research Disclosure Database Number 434009 teaches that which is disclosed above.

Research Disclosure Database Number 434009 teaches the applicator is a sponge or cloth soaked with the coating solution or a coating paste. Research Disclosure Database Number 434009 does not specifically teach the thickness of the coating layer on the applicator surface is 2.5 microns to about 1000 microns or 25 microns to about 100 microns. It would have been obvious to one having ordinary skill in the art at the time the invention was made to deposit a layer of coating composition on the applicator surface has a thickness of 2.5 to 1000 micron or 25 to 100 microns, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See M.P.E.P 2144. 05 IIB.

As for claim 6:

Research Disclosure Database Number 434009 teaches the applicator is a sponge or cloth soaked with the coating solution or a coating paste. The viscosity of the composition would obvious fall within the Applicant claimed range, absent any clear and convincing evidence and or arguments to the contrary.

7. Claims 9, 12-15 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Schueller et al. ('220) in view of Pacetti et al. (6,565,659).

Schueller et al. ('220) teach that which is disclosed above.

Schueller et al. teach a method of coating sent by applying a layer of composition onto the applicator, then transferring the coating from the applicator to the stent. Schueller et al. ('220) do not specifically teach leveling the composition so that the layer has a substantially uniform thickness.

Pacetti et al. ('659) teach a method of coating stent (abstract) by mounting the stent on a support assembly configured to reduce the amount of coating is applied to the regions where the stent (col. 3, line 1-10) is in contact with the support assembly. The acting of applying a coating material to a stent includes applying the coating material to a stent while rotating the stent about the longitudinal axis of the stent. Further, Pacetti et al. ('659) teach (col.5, line 5-7) the presence of shields in the support assembly cause the coating thickness to be uniform on the entire surface of the stent. It would have been obvious to one of ordinary skill in the art to use the shields in the support assembly in the coating method of Schueller et al. ('220) with the expectation of successful results, because Pacetti et al. ('659) teach a successful method of coating stent with uniform thickness.

As for claim 14:

The combined teachings of Schueller et al. ('220) and Pacetti et al. ('659) fail to teach the leveling the composition comprising directing a gas to the coating composition, the gas having

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sufficient air flow to reduce the profile of the composition. It would have been obvious to one having ordinary skill in the art at the time the invention was made to direct a gas to the coating composition to reduce the profile of the composition of the combined coating method of Schueller et al and Pacetti et al. ('659), since it has been held that merely changing a functional equivalent design involves only routine skill in the art. It would not provide a patentable feature to the claimed invention

As for claim 12:

Pacetti et al. ('659) teach the (col. 5, line 32-37) rotation of the stent can be from about 1 rpm to about 300 rpm, more narrowly from about 50 rpm to about 150 rpm.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being anticipated by Schueller et al. (US 2002/0050220).

Schueller et al. ('220) teach that which is disclosed above. Schueller et al. teach a method of coating a stent by depositing a layer of a composition on an application, transferring the composition to the stent, and rotating the applicator to coat the stent, Schueller et al. ('220) fail to specifically teach the rotational speed of the applicator is between 0.1 to 200 rpm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to deposit a layer of coating composition on the applicator surface and to rotate the applicator in the speed of 0.1 to 200 rpm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering an optimum or workable ranges involves only routine skill in the art. See M.P.E.P



### *Specification*

9. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

The applicant is requested to provide a more definitive abstract.

***Drawings***

10. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Erma Cameron/ whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erma Cameron/  
Primary Examiner  
Art Unit 1762

June 7, 2007